REMARKS

Claim Status

Claims 14-29 are pending in the application. Claims 18 and 26 have been canceled without prejudice to Applicant's rights to pursue the subject matters in a future application, and claims 14 and 22 have been amended. Applicant submits that there is no issue of new matter, and requests that the amendment be entered. Upon entry, claims 14-17, 19-25 and 27-29 will be pending and under examination in this application

Rejection Under 35 U.S.C. § 112, 2nd Paragraph

Claims 18 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The rejection is moot because claims 18 and 26 have been canceled without prejudice.

Rejection Under 35 U.S.C. § 103

Claims 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (J. Immunol. 163:3045-3052 (1999)) in view of Donzis et al. (U.S. Patent No. 5,519,009). The rejection is respectfully traversed.

The Examiner contends that the zymosan polysaccharide described by Yan et al. is identical to the carbohydrate described in the instant claims, and Donzis et al. was cited to provide teaching on solubilized glucan composition that can be administered orally.

First of all, Applicant submits that the zymosan polysaccharide described by Yan et al. is not identical to the glucan described in the instant claims. The present specification teaches a glucan that comprises a β-1,3 backbone and at least one β-1,3 side

chain linked to the backbone by a β-1,6 glycosidic bond. Because the side chains are β-1,3-linked in addition to the β-1,6 glycosidic bond with the backbone, there are at least two glucose units linked together in a β-1,3 manner on each side chain. For clarification, claims 14 and 22 have been rewritten to recite "wherein the β-glucan comprises a β-1,3 backbone and at least one β-1,3 side chain of two or more glucose units linked to the backbone by a β-1,6 glycosidic bond."

In contrast, the Yan glucan is described as a β-1,3 glucan (page 3046, left bottom paragraph) without mention of any side chain or β-1,6-linkages. Although the Yan article refers to β-glucan Biological Response Modifiers (BRM) as having "backbone structures of β-1,3-linked D-glucose (β-1,3-D-glucan) with β-1,6-linked side chains of β-1,3-D-glucan of varying sizes and frequencies along the backbone (2)" (page 3045, first paragraph), the reference 2 (Bohn et al., 1995, Carbohydrate Polymers, 28: 3-14) actually describes the BRM's as "(1→3)-β-D-glucans that have β-D-glucopyranosyl units attached by (1→6) linkages as single unit branches" (Abstract). Therefore, even if the Yan glucan is one of those BRM's, the side chains consist of only one glucose unit, clearly different from the side chains of the presently claimed glucan.

Moreover, one example in the present specification shows that the test glucan displays little anti-tumor effect by itself (*see* Figure 5; page 7, line 35). In contrast, Yan et al. teach a zymosan polysaccharide, SZP_g, that causes a 47% reduction in tumor weight in mice receiving SZP_g alone as compared to the PBS control group (*see* Figure 3 and legend of Figure 3). Hence, in view of the different biological activities, the zymosan

polysaccharide described by Yan et al. is different from the glucan described in the instant claims.

One reason for the difference between the zymosan polysaccharide of Yan et al. and the glucan of the present invention is that the zymosan polysaccharide of Yan et al. and the present glucan are produced by different methods. Yan et al. teach:

> polysaccharides are eluted from zymosan by heating to 95°C in 90% formic acid for 20 min. After discarding large polysaccharides precipitating with 70% ethanol, a small polysaccharide fraction is isolated by precipitation with 80% ethanol. After digestion with α-mannosidase and removal of anionic proteins by Mono-Q fast protein liquid chromatography, a uniform-sized soluble polysaccharide is isolated by chromatography with S-200HR. (page 3046, left column, paragraph under SZP)

In contrast, the glucan of the present invention is prepared by a different method. The present specification teaches that glucans having β-(1-3) and β-(1-6) linkages are prepared by the process described in U.S. Patent No. 5,233,491 and 4,810,646 (page 12, lines 15-22). The '491 patent teaches that "the general method for the production of glucan from yeast involves extraction with alkali followed by extraction with acid" (column 1, lines 33-35). Thus, it is clear that the zymosan polysaccharide of Yan et al. is not prepared by a method comprising a step of alkali extraction.

In summary, the glucan of Yan et al. and the glucan of the present invention are clearly different because they have been prepared by different methods and do not have the same biological activities. Moreover, as the Examiner pointed out on page 7 of the Office Action, "Yan et al. does not disclose a composition containing both

a beta glucan and an antibody." It would not have been obvious to one of ordinary skills in the art at the time of the invention to prepare a composition comprising an antibody and the instant glucan which is structurally different from that of Yan et al. Although the method of Yan et al. comprises concurrently administering an antibody and the glucan of Yan et al., one of ordinary skills in the art would not have been motivated to prepare a composition comprising an antibody and the instant glucan, which is structurally different from that of Yan et al. and therefore possesses different properties as discussed above.

Since the primary reference Yan et al. does not teach or suggest each and every aspect of the present invention, the combination of Yan et al. and Donzis et al. would not render the present invention obvious. Accordingly, Applicant respectfully requests that the rejection to claims 14-29 under 35 U.S.C. 103(a) be withdrawn.

CONCLUSION

Applicant submits that the present Proposed Amendment has adequately addressed the rejections raised by the Examiner in the August 11, 2008 final Office Action. Therefore, the application is in full compliance with all requirements. Accordingly, Applicant respectfully urges the Examiner to place this application in condition for allowance.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below. If any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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